ATTORNEY DOCKET NUMBER: 2004117-0008 (NEMC 197-DIV)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Carr, et al.

Examiner:

TBA

Serial No.:

TBA

Group Art Unit:

TBA

Filed:

April 21, 2004

For:

NOVEL CHIMERIC ANALGESIC PEPTIDES

Mail Stop: Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Certificate of Mailing				
I certify that this correspondence is bein	g deposited with the United States Postal Service with sufficient postage as First			
Class Mail in an envelope addressed to: VA 22313-1450 April 21, 2004	Commissioner for Parents, Mail Stop Patent Application, P.O. Box 1450, Alexandria,			
Date	Signature Kenneth R. Maben			
Typed or Printed Name of person signing certificate				

Sir:

STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

[X] An *original* Information Disclosure Statement; or

[] A supplemental Information Disclosure Statement.

Express Mail No.: EV 314104732 US

3689165v1

Page 1 of 6

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

[X] Pursuant to 37 CFR § 1.97(b); no fee or certification is required:			CFR § 1.97(b); no fee or certification is required:	
	[X] Within three months of the filing date of a national application oth			
		a conti	nued prosecution application under § 1.53(d);	
	[]	Within	three months of the date of entry of the national stage as set forth	
		in § 1.491 in an international application;		
	[]	Before	the mailing of a first Office action on the merits; or	
	[]	Before	the mailing of a first Office action after the filing of a request for	
		contin	ued examination under § 1.114.	
[] Pursuant to 37 CFR § 1.97(c) after the dates listed about			7 CFR § 1.97(c) after the dates listed above but before the mailing	
	date of any of a final action under § 1.113, a notice of allowance under § 1.311, or			
	otherwise closes prosecution in the application; Applicant hereby			
	either:			
	[] Certifies that either:		es that either:	
		[]	each item of information contained in the information disclosure	
			statement was first cited in any communication from a foreign	
			patent office in a counterpart foreign application not more than	
			three months prior to the filing of the information disclosure	
			statement; or	
		[]	That no item of information contained in the information	
			disclosure statement was cited in a communication from a foreign	
			patent office in a counterpart foreign application, and, to the	

Express Mail No.: EV 314104732 US 3689165v1

Page 2 of 6 Atty

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

			the information disclosure statement.; or
	[]	Includ	les herewith the fee set forth in § 1.17(p).
[]	Pursu	ant to 3'	7 CFR § 1.97(d), after the mailing date of any of a final action under
	§ 1.11	3, a not	ice of allowance under § 1.311, or an action that otherwise closes
	prose	cution in	n the application; Applicant hereby both:
	[]	Certif	ies that either:
		[]	each item of information contained in the information disclosure
			statement was first cited in any communication from a foreign
			patent office in a counterpart foreign application not more than
			three months prior to the filing of the information disclosure
			statement; or
		[]	That no item of information contained in the information
			disclosure statement was cited in a communication from a foreign
			patent office in a counterpart foreign application, and, to the
			knowledge of the person signing the certification after making
			reasonable inquiry, no item of information contained in the
			information disclosure statement was known to any individual

Express Mail No.: EV 314104732 US 3689165v1

Page 3 of 6

the information disclosure statement.; and

designated in § 1.56(c) more than three months prior to the filing of

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- [X] A copy of each cited reference not indicated with a check mark () is included;
- [X] Copies of references indicated with a check mark () on the attached form PTO1449 are not included pursuant to 37 CFR § 1.98(d) because they were
 previously provided to the United States Patent Office in an Information

 Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted
 in the following patent application that is relied upon in the present case for an
 earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status
09/428,692	October 28, 1999	Allowed

[] Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the aboveidentified application:

Applicant certifies that the Information Disclosure Statement either:

[] Does not contain non-English language citations;

Does contain non-English language citations, of which the following is a concise

Express Mail No.: EV 314104732 US 3689165v1

Page 4 of 6

explanation:

[] Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a

representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an

admission that the information cited in the statement is, or is considered to be, material to

patentability as defined in § 1.56(b).

The submission of this Information Disclosure Statement shall not be construed as a

representation that the information cited in the Statement is, or is considered to be, in fact, prior

art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other

information, in reaching a determination concerning the patentability of the present claims;

2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the

cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark

Office during the examination of this application; and

3. The citations for the patent(s) and publication(s) be printed on any patent which

issues from this application.

Express Mail No.: EV 314104732 US

3689165v1

Page 5 of 6 Atty Docket No.: 2004117-0008

Client Reference: NEMC 197-DIV

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

Dated: April 21, 2004

Nadège M. Lagneau, Ph.D.

Agent for Applicant Reg. No. 51,908

PATENT GROUP CHOATE, HALL & STEWART Exchange Place 53 State Street Boston, Massachusetts 02109

Tel: (617) 248-5000 Fax: (617) 248-4000

Express Mail No.: EV 314104732 US

3689165v1

Page 6 of 6

Form PTO-1449 U.S. Department of Commerce (REV. 8-83) Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT		Trademark Office	Atty. Docket: 2004117-0008 (NEMC 197-DIV)	In re Application No. TBA	
		E STATEMENT	Applicant: Carr et al.		
(Use several sheets if necessary)			Filing Date: April 21, 2004	Group: TBA	
U. S. PATENT D	OCUMENTS				
Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	5,891,842	Kream	04/06/99		
U. S. PATENT A	PPLICATIONS				
	Document No.	Applicant	Filing Date		
FOREIGN PAT	ENT DOCUMENTS				•
Examiner's Initials	Document No.	Country	Publication Date	Translation	
				Yes	No
Examiner's Initials					
	Carr et al., "Neural Blockade in Clinical Anesthesia and Management of Pain", Third ed., pp. 915-983, 1998.				
	Foran et al., "Inhibition of Morphine Tolerance Development by a Substance P-Opioid Peptide chimera", <i>J. Pharmacol. Exp. Ther.</i> , 295 (3): 1142-1148, 2000.				
	Foran et al., "A substance P-opioid chimeric peptide as a unique nontolerance-forming analgesic", <i>Proc. Natl. Acad. Sci.</i> , 97 : 7621-7626, 2000.				
	Foran et al., "Chimeric peptide for the treatment of acute and chronic pain", Anesthesiology (Hagerstown), Vol. 91, No. 3A, 1999, p. A944 XP000996135 Annual Meeting of the American Society of Anesthesiologists; Dallas, Texas, USA; October 9-13, 1999 ISSN: 0003-3022.				

Express Mail No.: EV 314104732 US 3689083v1

Page 1 of 3

Form PTO-1449 (REV. 8-83)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket: 2004117-0008 (NEMC 197-DIV)	In re Application No. TBA		
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: Carr et al.			
		Filing Date: April 21, 2004	Group: TBA		
	Foran S., "Characterization of Novel Chimeric Analgesic Peptides", Ph.D. Dissertation, Tufts University, Sackler School of Graduate Biomedical Sciences, September 2000.				
	✓ Hyden et al., Eur. J. Pharmacol., 86 :95-98, 1983.				
	Hyden et al., J. Pharmacol. Exp. Ther., 226:398-404, 1983.				
-	✓ Kream et al., Proc. Nat'l. Acad. Sci. USA, 90	:3564-3568, 1993.			
	Langel et al., "Design of chimeric peptide ligands to galanin receptors and substance P receptors", <i>International Journal of peptide and protein research</i> , DK, Munksgaard, Copenhagen, 39(6): 516-522, 1992.				
	Lei et al., "Opioid and neurokinin activities of substance P fragments and their analogs", Eur. J. Pharmacol., 193(2):209-215, 1991.				
	Lipkowski et al., "Neuropeptides: Peptide and Nonpeptide Analogs", Gutte ed., Academic Press pp 287-320, 1995.				
	Lipkowski et al., "An approach to the self regulatory mechanism of substance P actions: II. Biological activity of new synthetic peptide analogs related both to enkephalin and substance P", Life Sciences, 33(Sup. I): 141-144, 1983.				
	Lipkowski et al., "Opioid Peptide Analogues: Reconsideration as a Potentially New Generation of Analgesics", <i>Polish J. Chem.</i> , 68 : 907-912, 1994.				
	Lipkowski et al., "Peptides as receptor selectivity modulators of opiate pharmacophores", J. Med. Chem., 29: 1222-1225, 1986.				
	Lipkowski et al., "Benzomorphan alkaloids, natural peptidomimetics of opioid peptide pharmacophores", Lett. Peptide Res., 2: 177-181, 1995.				
	Lipkowski et al., "Biological activities of a peptide containing both casomorphin-like and substance P antagonist structural characteristics", in Casomorphins and related peptides. Recent developments, V. Brantl, H. Teschemacher, eds, VCH, Weinheim, pp. 113-118, 1994.				
	Maszczynska et al., "Dual funstional interactions of Substance P and opioids in nociceptive transmission: Review and Reconciliation", <i>Analgesia</i> , 3:259-268, 1998.				
	Maszczynska et al., "Alternative forms of inte nociceptive transmission", Letters in Peptide Scientification	raction of substance P a ence, 5: 395-398, 1998.	and opioids in		
	Misterek et al., "Spinal co-administration of pantinociceptive effect of the opioid peptide biphal	eptide substance P anta lin", <i>Life Sciences</i> , 54 (1	gonist increases 4): 939-944, 1994.		
	Patent Abstracts of Japan, Vol. 1999, No. 8, 3	0 June 1999 & JP 1106	0598 A (ASASHI		

Page 2 of 3

Express Mail No.: EV 314104732 US 3689083v1

				
Form PTO-1449 (REV. 8-83)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket: 2004117-0008 (NEMC 197-DIV)	In re Application No. TBA	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: Carr et al.		
		Filing Date: April 21, 2004	Group: TBA	
	GLASS CO LTD), 2 March 1999 abstract, page	3, Formula 1(A).		
	Schiller et al., J. Med. Chem., 36:3182-3187	, 1993.		
	Silbert et al., "Analgesic activity of a novel b via different routes of administration", Agents ar	ivalent opioid peptide ond Action, 33:382-387,	compared to morphine 1991.	
	Silbert et al., <i>Prog. Clin. Biol.</i> , 328:485-488,	1990.		
	Sizheng et al., "Opioid and neurokinin activities of substance P fragments and their analogs", Eur. J. Pharmacology, 193: 209-215, 1991.			
	Ward et al., J. Med. Chem., 33:1848-1851, 1	990.		
	Zadina et al., <i>Life Sci.</i> , 55 :461-466, 1994.			
		i		

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Express Mail No.: EV 314104732 US

3689083v1

EXAMINER

Page 3 of 3

Attorney Docket No.: 2004117-0008 Client Reference No.: NEMC 197-DIV

DATE CONSIDERED